Boston Scientific International S.A.
ZAC Paris Nord II/Bât Emerson - 33 rue des Vanesses – 93420 Villepinte
Siège social : Parc du Val Saint Quentin – 2 rue René Caudron
78960 Voisins le Bretonneux – France

Tel 33 (0)1 48 17 47 00
Fax 33 (0)1 48 17 47 01
www.bostonscientific.com

«Hospital_Name»
«Users_Name»- «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Reference: 92378480 -FA 29 April 2019

Urgent Field Safety Notice - Medical Device Withdrawal
Xenform™ Soft Tissue Repair Matrix
Uphold™ Lite with Capio SLIM Vaginal Support System
Polyform™ Synthetic Mesh
Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior

Dear «Users_Name»,

Boston Scientific is implementing a withdrawal of the following products indicated for transvaginal placement of pelvic organ prolapse:

- Xenform™ Soft Tissue Repair Matrix
- Uphold™ LITE with Capio SLIM Vaginal Support System
- Polyform™ Synthetic Mesh
- Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior

On Tuesday, April 16, 2019, the United States Food and Drug Administration (FDA) ordered all manufacturers of surgical mesh for transvaginal repair of pelvic organ prolapse to stop selling products immediately and withdraw all products from the US market. FDA does not believe sufficient clinical evidence is available to assure the benefits of these devices outweigh their probable risks; for the US market this withdrawal was specific to only Xenform™ Soft Tissue Repair Matrix and Uphold™ LITE with Capio SLIM Vaginal Support System

Based on this FDA decision and the global regulatory environment regarding transvaginal mesh for this indication, BSC has now made the decision to voluntarily withdraw from inventory, all products listed above from the rest of the world, which are indicated for the transvaginal repair of pelvic organ prolapse.

Clinical Recommendations

Boston Scientific recommends that patients who have had transvaginal mesh placed for the surgical repair of pelvic organ prolapse should continue with their annual, other routine check-ups, and follow-up care. There is no need to take any additional action if patients are satisfied with their surgery and are not having any complications or symptoms.

Next Steps
Following is a list of affected products in scope of this action, all batches of which are to be withdrawn. No other BSC products are impacted by this withdrawal.

Attached to this letter is a specific listing of products which we have record of shipping to your facility. Please segregate the product immediately and return it to Boston Scientific in accordance with the enclosed instructions.

AFFECTED PRODUCT LISTING

UPN	Description	GTIN	Batch
M0068302410	Xenform™ Tissue Repair Matrix - 2cm X 7cm	8714729775133	All batches
M0068302430	Xenform™ Tissue Repair Matrix - 4cm X 7cm	8714729774464	
M0068302450	Xenform™ Tissue Repair Matrix 6cm X 10cm	8714729773764	
M0068302470	Xenform™ Tissue Repair Matrix 8cm x 12cm	8714729774198	
M0068318170	Uphold™ LITE with Capio SLIM Vaginal Support System	8714729839200	
M0068402400	Polyform™ Synthetic Mesh, 10cm x 15cm, box 1	08714729121305	
M0068402410	Polyform™ Synthetic Mesh, 15cm x 20cm, box 1	08714729767015	
M0068318150	Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior	08714729854548	

Further distribution or use of any remaining product affected by this action should cease immediately.

INSTRUCTIONS:
1- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- **Please complete the attached Verification Form** even if you do not have any product to return.

3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **15 May 2019**.

4- **If you have products to return,** please package them in an appropriate shipping box and **contact** «Customer_Service_Tel» **of your local Boston Scientific office,** to arrange return.

5- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the high-quality standards that you expect from Boston Scientific.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

Please Complete the form even if you do not have any affected product
& send it to Your Local Office: **«Customer_Service_Fax_Number»**

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Verification Form – Medical Device Withdrawal
"Name of the Product"
92378480-FA

---

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated «Date_notif_sent».

2. **Boston Scientific records indicate you have received the following affected product** *(additionally please check inventory against complete list of affected product provided)*

Product Description	**Material N° (UPN)**	**Lot / Batch N°**	**Customer PO**	**Qty Sent** (Units)	**Qty to return** (Units)
«DESCRIPTION»					

3. We confirm that all areas where affected product could be located have been checked.

4. **TICK ONE OF THESE STATEMENTS*****, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»

- ❑ We do not have any affected product.
- ❑ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please* ***add the UPN, Lot/Batch/Serial number and the quantity to return.***

TO RETURN PRODUCTS:
1. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

NAME* _____Title _____

Telephone _____ Department _____

Customer' **SIGNATURE*** _____ **DATE*** _____
* Required field dd/mm/yyyy